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10/521,040	08/16/2005	Herman Jan Tijmen Coelingh Bennink	0470-050079	6630

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EXAMINER	
CHUI, MEI PING	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,040	COELINGH BENNINK ET AL.	
	Examiner	Art Unit	
	Helen Mei-Ping Chui	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-62* is/are pending in the application.

4a) Of the above claim(s) *55-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/09/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Applicant's election with traverse of invention I, which encompasses claims 25-54 in the reply filed on 06/025/2007 is acknowledged. The traversal is on the ground(s) that the claimed aromatase inhibitor in invention II cannot be directed to a product for inhibiting conception (see page 2 of the Remarks). It is noted to the Applicant that the technical feature links the inventions I and II is an estrogenic component of recited formula (see claims 25, 35 and 45 for invention I verses claim 55 for invention II), not an aromatase inhibitor. Furthermore, the traversal is also on the ground(s) that there would not be a serious burden to examine all the claims together of the present application (see Page 3 of the Remarks). This is not persuasive because a search for a method of invention I will require searching for method whereas a search for a composition of invention II will require searching for product in different fields of the literature; thus constitutes a serious undue burden on the Examiner to examine all the claims together of the present application (see Page 3 of the Remarks).

It is also noted to the Applicant that the election of species requirement is withdrawn by the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 1-24 are cancelled. Accordingly, claims 25-54 are presented for examination on the merits for patentability as they read upon the elected subject matter and claims 55-62 directed to non-elected inventions are withdrawn.

It is noted that in claim 25, the term "method.which" is separated by a period. Applicant is required to correct the typographical error.

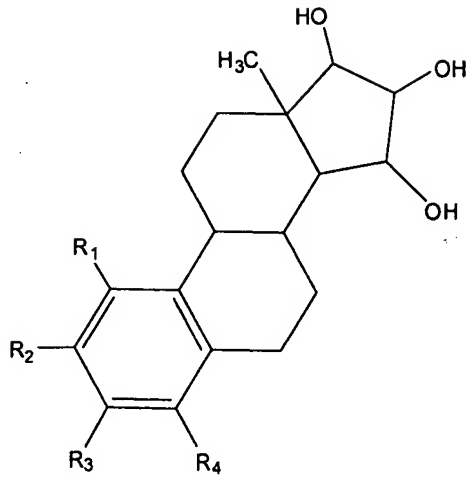
DOUBLE PATENTING

The nonstatutory double-patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-28 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 20-24 of co-pending U.S. Patent Application No. 10/532,320. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of claims 20 and 24 of co-pending U.S. Patent Application No. 10/532,320 instantly claimed subject matter where both instant and conflicting claims are drawn to a method of treating or preventing estrogen-sensitive tumors in a mammal comprising administering to said mammal an effective amount of an estrogenic component, wherein said estrogenic component represented by the formula below:



in which formula R_1, R_2, R_3, R_4 independently are a hydrogen atom, a hydroxyl group or an alkoxyl group with 1-5 carbon atoms, precursor capable of liberating a substance (conflicting claim 20) or the estrogenic substance (conflicting claim 24) described therein in the claims.

Therefore, one of ordinary skill in the art, at the time the claimed invention was made, would have readily recognized that claims 20-24 found in co-pending U.S. Patent Application No. 10/532,320 and claim 25 in the instant application are obvious variant and are not patentability distinct to each other.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 recites that said estrogen component selected from the group consisting of "precursors" capable of liberating a substance according to the aforementioned formula "when used in the present method" (instant claim 25, line 9-10).

Since the term "precursor" is not defined by the specification, and the specification does not provide a standard for ascertaining the requisite degree; therefore, one of ordinary skill in the art would not be reasonably apprised the intended limitation for the "precursor" in such a manner that whether the precursor is capable of liberating the estrogenic component only when used in the present method or it is also capable of liberating the estrogenic component when used in other methods. Applicant is advised to remove the term "when used in the present method" recited in instant claim 25.

In addition, claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 recites the limitation "an effective amount to suppress blood serum 17β-estradiol level to below 10 pg/ml" by an aromatase inhibitor. However, the term "an effective amount" is not defined by the specification, and the specification does not provide a standard for ascertaining the requisite degree. Therefore, one of ordinary skill in the art would not be reasonably apprised the intended limitation for what the effective amount is. Thus, it renders the claim indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement of the Invention

Claims 25-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 25-44 while being **enabling for treating** estrogen-sensitive tumors as claimed comprising administering a therapeutically effective amount of said estrogen compound with an aromatase inhibitor, **does not reasonably provide enablement for preventing** said estrogen-sensitive tumors in aforementioned method due to the diverse origination and causes of said tumors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Furthermore, claim 44, which co-administering an effective amount of aromatase inhibitor to suppress blood serum 17β-estradiol level to below 10 pg/ml, is not enabled.

An analysis of whether the scope of a particular claim(s) is actually supported by the disclosure in a patent application requires a determination of whether the disclosure, at the time of filing, contained sufficient information regarding the subject matter of the claim at issue so as to enable one skilled in the pertained art to use the claimed invention without undue experimentation. *In re Wands*, 8 USPQ 2d 140 (Fed. Cir. 1988). Therefore, the test of enablement is not whether experimentation is necessary, but rather, if experimentation is in fact necessary, whether it is reasonably considered to be undue. *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976). Determining the issue of enablement with respect to a claim is a question of law based on underlying factual findings. *In re Vaeck*, 20 USPQ 2d, 1444 (Fed. Cir. 1991). More particularly, there are many factors to be considered in determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, and whether any necessary experimentation is reasonably considered to be "undue". See *In re Wands* at page 1404. MPEP § 2164.01(a). The court in *In re Wands* set forth the following factors to be considered, which included, without limitation, the: 1). scope or breadth of the claims; 2). nature of the invention; 3). relative level of skill possessed by one of ordinary skill in the art; 4). state of, or the amount of knowledge in, the prior art; 5). level or degree of predictability, or a lack thereof, in the art; 6). amount of guidance or direction provided by the inventor; 7). presence or absence of working examples; and 8). quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the examiner's

position that one skilled in the art could not practice the invention without undue experimentation.

Scope or breadth of the claims:

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, the method of preventing estrogen-sensitive tumors by administering an effective amount of said estrogenic compound with an aromatase inhibitor to a mammal. However, Applicant is purporting that said estrogenic compound co-administered with an aromatase inhibitor in said method can effectively treat estrogen-sensitive tumors in a mammal, or can effectively prevent said estrogen-sensitive tumors from occurrence, even though the multitude of these diseases are diversely originated, implicate that all causes and factors that may give rise to said tumors can be treated or prevented by administering the combination of said estrogenic compound and an aromatase inhibitor.

Nature of the invention:

The nature of the invention is directed to a method of treating or preventing estrogen-sensitive tumors in a mammal, such as breast cancer, uterine cancer, endometriosis and so on as claimed, by administering an effective amount of said estrogenic compound and an aromatase inhibitor to a mammal. For claim 44, it is directed to a method for co-administration of an effective amount of aromatase inhibitor to suppress blood serum 17β-estradiol level to below 10 pg/ml.

State of, or the amount of knowledge in, the prior art:

It is known in the current state of the art that tumors arise from many different aspects and causes, such as diet, environment or genetics, for examples. Some of these factors are being assessed as risk factors that may increase the chance of developing cancer and some of these factors are being assessed as protective factors that may decrease the chance of developing cancer. Currently, the approach to cancer prevention is based on the assessment of risk factors and protective factors a person may encounter. However, some risk factors for cancer can be avoided, but some cannot. Likewise, increase the protective factors may only lower the risk of developing a cancer, but does not completely inhibit the occurrence of a cancer (see National Cancer Institute: Breast cancer prevention retrieved online 08/07/2007 from the internet http://www.cancer.gov/templates/doc.aspx?viewed=D972A74B-D25A-4F86-B8ED-33EB3C0450E4&version, page 1). For examples, as of to date, the cause for ovarian cancer is still unknown (see Medline Plus®: Medical Encyclopedia: Ovarian cancer retrieved online on 08/09/2007 from the internet https://www.nlm.nih.gov/medlineplus/ovariancancer.html, page 1 dated on 07/31/2007) or there is still no cure for endometriosis (see National Institute of Child Health and Human development, NIH Publication No. 02-2413 retrieved online on 08/09/2007). Since preventing a disease to occur, one must first know the cause that induces the occurring of such disease. However, currently there is still no known method that can truly prevent the occurrence of some diseases, such as estrogen-sensitive tumors, for example.

With respect to claim 44, the state of the art does not teach how much aromatase inhibitor is effective in relation to the treatment.

Amount of guidance or direction provided by the inventor:

Although the instant specification discloses that the administration of estetrol and tamoxifen (see specification, examples 2-5) for treating mammary tumor; it remains silent on the use of said estrogenic compound with an aromatase inhibitor, as claimed, for the prevention of said estrogenic-sensitive tumors.

For claim 44, the Examiner noticed that the instant specification discloses a pharmaceutical composition containing 0.05 mg of aromatase inhibitor anastrozole (see specification page 16, line 27-29 and page 17, line 1-3).

Presence or absence of working examples:

The specification provides some scientific data and working embodiments with respect to the administration of estetrol and tamoxifen for treating mammary tumors only (see specification, page 20-27: examples 2-5). However, in the specification, there is no working example or guidance provided for preventing the occurrence of claimed estrogen-sensitive tumors. In the same way, the specification does not provide any guidance or working embodiment with respect to the effective amount of aromatase inhibitor in order to suppress blood serum 17β-estradiol level to below 10 pg/ml, as claimed in claim 44.

Level or degree of predictability, or a lack thereof, in the art:

A high degree of unpredictability exists in the state of the art regarding how to prevent tumors formation. Risk factors evaluation, although, may help to avoid the chances of tumor formation; however, at this stage of the art, many of them are still an unsolved puzzle to the

scientific field or there is lack of knowledge in the art to prevent the occurrence of tumors due to some uncontrollable genetic risk factors. For example, women who have inherited genetic defect(s) or mutation in the *BRCA1* and *BRCA2* genes may have a higher risk of developing a breast cancer (see Breast Cancer Prevention retrieved online 08/07/2007 from the internet http://www.cancer.gov/cancertopics/pdq/prevention/breast/Patient/page 3) than those who does not inherit such genetic defect(s).

Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure:

One of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether said estrogenic compound when co-administering with an aromatase inhibitor in corresponding instant method does in fact effectively prevent the occurrence of said estrogenic-sensitive tumors.

For claim 44, the specification does not teach how the particular amount (0.05 mg) of aromatase inhibitor correlates to the suppression of blood serum 17β-estradiol level to below 10 pg/ml. Therefore, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to predict whether the amount of 0.05 mg or other amount of anastrozole is capable of suppressing blood serum 17β-estradiol level to below 10 pg/ml.

Therefore, in conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of scientific data and working embodiments regarding the prevention of estrogen-sensitive tumors, is not enabled because the specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

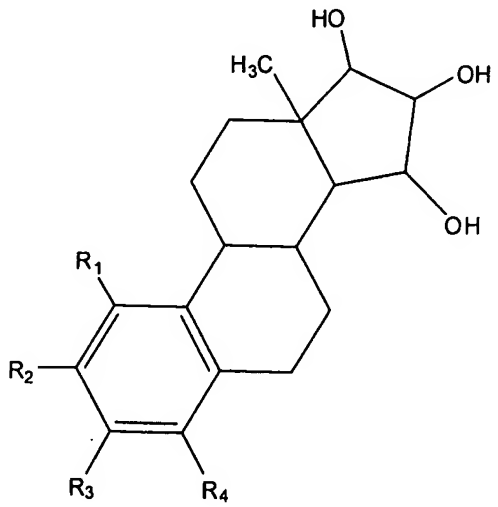
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25-28, 30-38, 40-48 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliesen J. (U.S. Patent Application Publication No. 2002/0156059) in view of Holinka et al. (Biology of Reproduction, 1980, 22, 913-926).

Applicant Claims

Applicant claims a method of treating or preventing estrogen-sensitive tumors in a mammal, wherein (**i**) said estrogen-sensitive tumors are selected from the group consisting of breast cancer, uterine cancer and those described therein (claims 25, 33, 35, 43, 45 and 53); (**ii**) by administering a therapeutically effective amount of said estrogenic compound (see structure below and claims 25, 35 and 45) with (**iii**) an aromatase inhibitor (claims 34, 35 and 54) or (**iv**) in an amount of at least 1 μg/kg of bodyweight per day of said estrogenic compound (claims 32, 42 and 52) having the structure as follows:

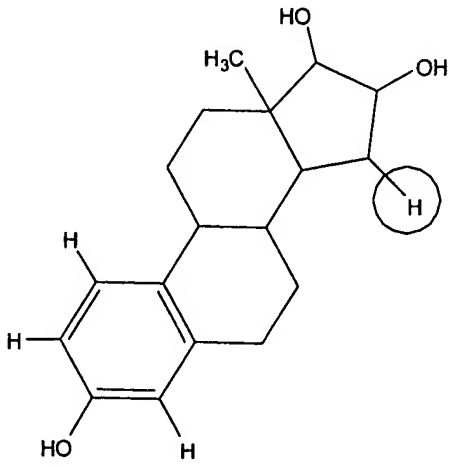


in which no more than 3 of the R_1, R_2, R_3 and R_4 groups in the structure are hydrogen atoms (claims 26, 36 and 46), or at least 3 of the groups of R_1, R_2, R_3 and R_4 in said estrogen structure are hydrogen atoms (claims 28, 38 and 48) or R_3 represents a hydroxyl group or an alkoxyl group (claims 27, 37 and 47) as described therein in the claims.

Determination of the scope and content of the prior art (MPEP 2141.01)

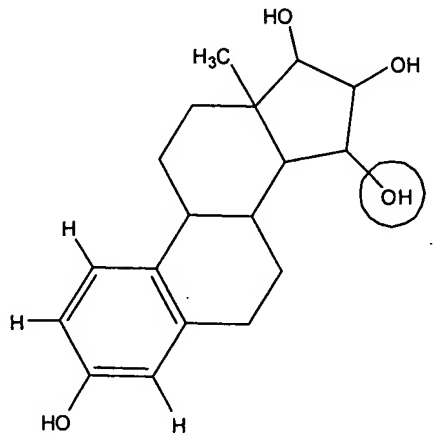
Elliesen, J. teaches the long term use of a pharmaceutical combination comprising at least one estrogen and at least one aromatase inhibitor for treating and reducing the risk of breast cancer. Elliesen, J. also implicitly teaches the administration of said combination without the present of GnRH (Abstract, line 8-10; page 1, paragraphs 0005 and 0006, line 1-4).

Elliesen, J. teaches that all natural and synthetic compounds that have estrogenic actions are suitable (page 2, paragraph 0019). Elliesen, J. also teaches that natural estrogens that have a longer action, such as estriol (see the structure below), are particular suitable (page 2, paragraph 0020, line 1-3).



Elliesen, J. teaches the daily dosage for an aromatase inhibitor are between 100-600 mg (column 2, paragraph 0017, line 1-2). Elliesen, J. further teaches the pharmaceutical combination can be provided for oral, subcutaneous or intravenous administration (page 2, paragraph 0034).

Holinka et al. teach a series of studies involving the estrogenic effects of estetrol (see the structure below) together with tamoxifen on the immature rat uterus in relation to other estrogens, such as estradiol or estriol (page 914, Introduction: paragraph 2, line 1-4).



Holinka et al. also teach that an amount of 50 μg of estetrol per 100 grams of body weight, which corresponds to 500 μg of estetrol per kilogram of body weight, was administrated daily to the immature rat uterus for the treatment (page 914, Introduction: paragraph 3, line 7; Material and Methods: Treatment, Tissue Collection and Storage section, line 10).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Elliesen, J. does not expressly teach the structure of an estrogenic compound, which containing up to four hydroxyl groups such as estetrol, described above. Elliesen, J. neither

expressly teaches an amount nor the duration of estrogenic compound that is being administered in said subject.

Finding of prima facie obviousness Rational and Motivation (MPEP 2142-2143)

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the teaching of Elliesen that utilize an oral form of an estrogen, i.e. estriol, and an aromatase inhibitor combination for treating and reducing the risk of breast cancer together with the teaching of Holinka et al. that estetrol has comparable estrogenic effect as the other natural estrogens, i.e. estriol, because estetrol is also capable of stimulating uterine growth. Therefore, one would have been motivated to choose estetrol instead of estriol with reasonable expectation of success because estetrol and estriol are structurally similar estrogens and have similar estrogenic properties.

Claims 29, 39 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliesen J. (U.S. Patent Application Publication No. 2002/0156059) in view of Holinka et al. (Biology of Reproduction, 1980, 22, 913-926) in further view of Spicer et al. (U.S. Patent No. 5,340,584) in combination.

The teachings of Elliesen J. and Holinka et al. have been set forth above. Elliesen, J. teaches the use of a combination comprising an estrogen and an aromatase inhibitor for treating and reducing the risk of breast cancer. Holinka et al. teach estetrol and estriol have comparable estrogenic effect *in vivo*.

However, the combined references of Elliesen J. and Holinka et al. do not teach the duration of estetrol is administered for a period of at least 30 days.

Applicant Claims

Applicant claims the administration of an strogenic compound is uninterrupted during a period of at least 30 days.

Determination of the scope and content of the prior art (MPEP 2141.01)

Spicer et al. teach a method to treat and to reduce the risk of breast cancer, ovarian cancer and endometrial cell proliferation (column 14, line 11-12, line 30, Table 1 and line 38-41) comprising administering an effective amount of an estrogen composition, such as estetrol, in a mammal for a period of about 2 months to about six months (column 20, claims 31-32).

Finding of prima facie obviousness Rational and Motivation (MPEP 2142-2143)

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the teaching of Spicer that estetrol can be administered for a period of more than 30 days in a mammal together with the methods of Elliesen and Holinka that utilize an estrogen, i.e. estetrol, and an aromatase inhibitor combination to treat or reduce the risk of breast cancer. Therefore, one would have been motivated to extend the administration of

estetrol for longer than 30 days with reasonable expectation of success because the administration period of estetrol used in the treatment of breast cancer is extendible.

In conclusion, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art fairly suggests the instant claims.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sinai M. Landau
Primary Examiner
Art 1616